Implementation Strategies in EHE HIV Projects

What they are
How to think about them
How to put them in your research

Implementation Science
Coordination, Consultation, & Collaboration Initiative

May 8, 2020
Dennis H. Li, Northwestern University
Patrick Sullivan, Emory University
Agenda

• Review basics about implementation strategies
• Discuss how strategies might fit into your projects
• Present examples of the focus on strategies in two HIV studies
• Q&A

Rewatch Byron’s Summit presentation here: https://isc3i.isgmh.northwestern.edu/summit/materials/
NIH Definition of Implementation Research

The scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings.

Implementation strategies should be central to your scientific inquiry, either as an intermediary goal (formative research) or as the primary focus (tests of strategy effectiveness, comparative implementation).
# Strategies: A Quick Review

<table>
<thead>
<tr>
<th>Clinical/preventive intervention</th>
<th>“The Thing” that improves people’s health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation</td>
<td>Doing “The Thing”</td>
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<tr>
<td>Implementation research</td>
<td>How to best do “The Thing”</td>
</tr>
<tr>
<td>Implementation strategies (AKA implementation interventions)</td>
<td>Other actions or “things” we do to help other people do “The Thing”</td>
</tr>
<tr>
<td>Implementation outcomes</td>
<td>How much / how well did others do “The Thing”</td>
</tr>
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Curran, 2020, *Implement Sci*
Strategies: A Quick Review

• Methods or techniques used to enhance adoption, implementation, sustainment, and scale-up/out of a program or practice

• Discrete (e.g., reminders)

• Multifaceted/packaged (e.g., training + consultation)
  • Often multilevel
  • Sometimes protocolized and branded (e.g., Getting To Outcomes)

• Target and/or interact with contextual determinants to achieve implementation outcomes ➔ mechanisms
  • Rarely one-to-one relationship between strategy and determinant
<table>
<thead>
<tr>
<th>Determinants</th>
<th>Implementation Strategies</th>
<th>Mechanisms</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Provider knowledge deficit</td>
<td>Education (provision of information)</td>
<td>Awareness-building, knowledge-acquisition</td>
<td>Feasibility, acceptability, appropriateness, adoption</td>
</tr>
<tr>
<td>Provider skill deficit</td>
<td>Training (teaching &amp; practice with corrective feedback)</td>
<td>Skill acquisition, refinement, mastery</td>
<td>Fidelity to EBP</td>
</tr>
<tr>
<td>Turnover</td>
<td>Train-the-trainer</td>
<td>Continuous on-site expertise available for consultation</td>
<td>Sustainability</td>
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<tr>
<td>Provider engagement</td>
<td>Clinical champion-led implementation team</td>
<td>Implementation climate</td>
<td>Feasibility, acceptability, appropriateness</td>
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<tr>
<td>Unstandardized clinical care options</td>
<td>Guidelines</td>
<td>Clarity of clinical care</td>
<td>Fidelity</td>
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Smith, 2019; Powell, 2019
Strategies: A Quick Review

Evidence-based clinical or preventive intervention – 7 Ps:

• Pill (PrEP)
• Program (PROMISE)
• Practice (routine HIV screening in clinical settings)
• Principle (Treatment as Prevention)
• Product (condom)
• Policy (housing for people at high risk for HIV)
• Procedures (male circumcision)

Evidence-informed strategies (system interventions) – ERIC categories:

o Engage consumers
o Use evaluate & iterative strategies
o Change infrastructure
o Adapt & tailor to context
o Develop stakeholder interrelationships
o Utilize financial strategies
o Support clinicians
o Provide interactive assistance
o Train & educate stakeholders

Strategies Should Be Central to Your Implementation Research

• Identifying determinants

• Selecting, developing, or adapting strategies

• Piloting or evaluating strategies

• Comparing strategies

  o Understanding why and how strategies work
Strategies Should Be Central to Your Implementation Research

- Identifying determinants
- Selecting, developing, or adapting strategies
- Piloting or evaluating strategies
- Comparing strategies
  - Understanding why and how strategies work
- CFIR–ERIC matching tool
- www.healthsystemsevidence.org
- Strategy selection methods

Methods to Improve the Selection and Tailoring of Implementation Strategies

Byron J. Powell PhD, Rinad S. Beidas PhD, Cara C. Lewis PhD, Gregory A. Aarons PhD, J. Curtis McMillen PhD, Enola K. Proctor PhD & David S. Mandell ScD

Strategies Should Be Central to Your Implementation Research

• Identifying determinants

• Selecting, developing, or adapting strategies

• Piloting or evaluating strategies

• Comparing strategies

  o Understanding why and how strategies work

• Specify implementation strategies
https://impsciuw.org/implementation-strategies
Strategies Should Be Central to Your Implementation Research

- Identifying determinants
- Selecting, developing, or adapting strategies
- Piloting or evaluating strategies
- Comparing strategies
  - Understanding why and how strategies work

- Select an appropriate study design
- Designs for Implementation Research Studies
  Including Pilot, Small-n, and Developmental

- Track strategy use
- Tracking implementation strategies: a description of a practical approach and early findings
Strategies Should Be Central to Your Implementation Research

- Identifying determinants
- Selecting, developing, or adapting strategies
- Piloting or evaluating strategies
- Comparing strategies
  - Understanding why and how strategies work

- Specify mechanisms and measure everything

- Draw from theory
Two HIV Examples

1. Identifying implementation strategies for PrEP scale-up based on determinants
2. Comparing two delivery approaches of an eHealth HIV prevention program
Implementation Strategies to Increase PrEP Uptake in the South

CFAR Implementation Science Initiative Webinar

May 8, 2020
County-randomized comparative implementation trial of two delivery strategies for an evidence-based eHealth HIV prevention program
Diagnoses of HIV Infection among Male Adults and Adolescents, by Transmission Category, 2010–2016—United States and 6 Dependent Areas

Diagnoses of HIV Infection among MSM by Age at Diagnosis, 2010–2016—United States and 6 Dependent Areas
Available EBIs were not commensurate

- Few programs designed specifically for YMSM
- Programs were in-person individual or group-based
- In response, Mustanski et al. developed Keep It Up!
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<td>5</td>
<td>6</td>
<td>7</td>
<td>(3 m)</td>
<td>(6 m)</td>
</tr>
<tr>
<td>Healthy person (optionally location specific)</td>
<td>Hooking Up Online</td>
<td>Soap Opera</td>
<td>Bar/Club</td>
<td>Dating</td>
<td>Healthy Communication</td>
<td>Goal Setting</td>
<td>Regular testing. Biomed prevention. Goal review</td>
<td>Prevention in relationships</td>
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**Healthy Communication Goal Setting**

**Regular testing. Biomed prevention. Goal review**

**Prevention in relationships**

**BAD TIMING**

**GOOD TIMING**

**have fun. stay safe. keep it up!**
NIMH R34 to develop and demonstrate feasibility and acceptability in Chicago, IL

CDPH-funded service implementation

NIDA and NIMH R01 to test efficacy in three cities with behavioral and biomedical outcomes in Jackson, MI

ViiV-funded service implementation

NIMH/NIDA/OD R01 to compare two national implementation strategies with behavioral and biomedical outcomes
Evidence and Rationale for KIU! 3.0

- In the multisite RCT, found to be acceptable and effective among racially diverse young MSM ages 18–29
- Demonstrated significant effects on a biomedical outcome (40% reduction in STIs at 12 months post-intervention)
- Now designated as “Best Evidence” by CDC

Why an implementation trial?
- Over the years, made interesting anecdotal observations around implementation
- eHealth is an opportunity for “low cost interventions with high reach potential”
- Many other eHealth HIV interventions currently being supported by NIH for development and efficacy testing
- How to scale up eHealth programs is still largely unknown
- Need to maximize return on investment
Specific Aims

Aim 1: Compare two implementation strategies using a cluster randomized trial. The type III hybrid implementation-effectiveness design prioritizes empirical comparison of implementation strategies while also collecting evidence of effectiveness.

• Strategy 1: Traditional model of community-based organizations competing for funding to implement KIU! in their routine testing with YMSM.
• Strategy 2: Innovative direct-to-consumer where HIV testing and intervention delivery is done remotely.

Aim 2: Examine adoption characteristics that explain variability in implementation outcomes. Drawing from CFIR we will examine domains such as county characteristics, adaptations, support from organization leadership, and approach to planning adoption.

Exploratory aim: Explore sustainment of KIU! at the completion of the study. CBOs will be provided with materials to facilitate applying for ongoing funding, and we will examine factors that predict applying for funding and ongoing sustainment. In the DTC arm, we will explore sustainment strategies through consultation with CDC, CBA providers, health departments, and Health 2.0 businesses.
Study Design

- **Effectiveness–implementation hybrid type 3 design**
  - Primary focus: compare two strategies on implementation outcomes
    - Direct-to-consumer (DTC)
    - Community-based organization (CBO)
  - Secondary focus: ensure KIU! is still effective on individual outcomes

- **Cluster-randomized trial**
  - 66 counties with most YMSM
  - CBO:DTC strategy, 2:1 randomization
  - RFP for CBO counties
  - Prioritizing pragmatic practices
CBO vs. DTC counties – Cohort 1
<table>
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<tr>
<th>Team</th>
<th>Delivery of direct-to-consumer (DTC) strategy</th>
<th>Delivery of community based organization (CBOs) strategy</th>
<th>Technology</th>
<th>Methodology</th>
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<td>Purpose</td>
<td>Online advertising and recruitment of YMSM and delivery of KIU in the direct-to-consumer arm.</td>
<td>Distribute request for proposals to CBOs, evaluate and select grantees, provide training and technical assistance.</td>
<td>Develop and support KIU intervention content and the technology platform that will allow for the delivery of KIU across both implementation strategies.</td>
<td>Oversee collection of outcome data from YMSM as well as DTC, CBO and technology teams, and CBO staff. Provide expertise in implementation science, health economics, and statistics. Perform all analyses.</td>
</tr>
<tr>
<td>Leads and Scientific Members</td>
<td>Macapagal</td>
<td>Benbow</td>
<td>Mustansi (lead), Saber</td>
<td>Brown (lead of implementation science methodology), Schackman (lead of health economics), and Janulis (lead of statistical analyses). Smith, Linas, and Murphy (members)</td>
</tr>
<tr>
<td>Supporting Research Centers</td>
<td>Institute for Sexual and Gender Minority Health and Wellbeing (ISGMH)</td>
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<td>Center for Behavioral Intervention Technology (CBIT)</td>
<td>Center for Prevention Implementation Methodology (Ce-PIM), Center for Health Economics of Treatment Interventions for Substance Use Disorders, HCV, and HIV (CHERISH), Third Coast Center for AIDS Research (CFAR)</td>
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Framework to translate research into practice with focus on:

- **Reach**
- **Effectiveness**
- **Adoption**
- **Implementation**
- **Maintenance**

Widely used in implementation science and applied to eHealth and HIV prevention

Recommendation to use mixed-methods approaches when assessing RE-AIM elements

**KIU!** collects:

- **Quantitative data** on Reach, Effectiveness, and Implementation in Aim 1 and Maintenance at study end
- **Mixed-methods data** on Adoption in Aim 2
Adoption – CFIR Mixed Methods

• CFIR - Evaluate factors from 5 domains:
  1. Outer setting (county characteristics, network links to other orgs, policies & incentives)
  2. Inner setting (implementation support from CBO leaders, implementation climate, and implementation culture)
  3. Characteristics of users (YMSM demographics and acceptability of KIU!)
  4. Characteristics of the intervention (local adaptations, staff perceptions of quality, and relative advantage over alternatives)
  5. Process characteristics

• CFIR data collected in waves => implementation (Wave 0/1) and then 4, 12, and 24 months following
  • Not all factors assessed at each wave – selected based on phase of implementation
  • Mix of quantitative and qualitative measures
Strategy Specification

Absent a Determinants Assessment – Scaling Up
**KIU! 3.0 Implementation Research Logic Model (IRLM)**

**DTC-Arm**

**Determinants**
- Characteristics of individuals
- Characteristics of providers
- Characteristics of organizations
- Characteristics of systems

**Implementation Strategies**
- Inter-sectoral involvement
- Mobilization of resources
- Establishment of partnerships

**Mechanisms**
- Linking to resources
- Routine contacts
- Patient communication platforms
- Consumer engagement

**Outcomes**
- Increased knowledge of KIU
- Increased availability of KIU among people at risk
- Increased network of service providers
- Increased support among CBOs
- Successful integration of KIU

**CBO-Arm**

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- Characteristics of individuals
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- Increased support among CBOs
- Successful integration of KIU

**Note:**
- Increased knowledge of KIU
- Among those delivering it
- Increased availability of KIU among people at risk
- Increased network of service providers for wrap-around services
- Increased support among CBOs implementing KIU
- Successful integration of KIU (low burden on staff and CBO resources)
Select Implementation Strategies

Northwestern
Adapt and tailor to context
• Tailoring intervention to CBOs

Utilize financial strategies
• Monetary support to CBOs

Develop stakeholder interrelationships
• Identify and prepare champions

Train and educate stakeholders
• Develop educational materials
• Training providers on KIU! & recruitment
• Ongoing capacity building assistance

Change infrastructure/support clinicians
• Hosts and maintains technology

Agency – Adapt and tailor to context

Utilize financial strategies
• Incentive structures

Develop stakeholder interrelationships
• Links to resources

Train and educate stakeholders
• Train new staff, ongoing training

Support clinicians
• Reminders/reports to staff

Engage consumers
• Outreach to YMSM
• Intervene to enhance uptake, adherence

DTC

Select Implementation Strategies

Northwestern
Utilize financial strategies
• Provide free at-home HIV/STI tests
• Non-monetary incentives

Develop stakeholder interrelationships
• Engage local CBOs, HDs, advocacy groups, researchers for referrals and recruitment strategies
• Links to resources

Train and educate stakeholders
• Training RAs and coordinators

Change infrastructure/support clinicians
• Custom-built patient tracking system
• Participant communication platform

Engage consumers
• Streamlined recruitment and enrollment with minimal staff interaction
• Advertise via social media, dating apps
• Routine contacts with, monitoring by NU
• Intervene to enhance uptake, adherence

Select Outcomes

Reach
• Proportion of YMSM in county screened for KIU!
• Proportion of invited YMSM who begin KIU!
• Proportion of KIU! participants that are Black or Latino

Implementation
• Intervention acceptability
• Mean number of KIU! modules completed by participants
• Cost of intervention delivery per participant
• Cost of intervention delivery per infection averted

Adoption & Maintenance not comparable between arms

Effectiveness
• Change in unprotected sex
• 12-mo rectal STI incidence
• 12-mo PrEP initiation
• 1+ HIV test(s) over 12 mos
### Select Implementation Strategies

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### KIU! Platform

- **Engage consumers**
  - Participant orientation
  - Automated reminders sent from system
- **Change infrastructure/support clinicians**
  - Custom-built patient tracking system

### Mechanisms

#### CBO: Tailoring some content and allowing adaptation of delivery at the CBO level increases CBO staff’s positive attitudes, ownership, and buy-in about KIU (e.g., acceptability, appropriateness, intervention-level determinants) and potentially fit to local YMSM needs.

#### Reach
- Proportion of YMSM in county screened for KIU!
- Proportion of invited YMSM who begin KIU!
- Proportion of KIU! participants that are Black or Latino

#### Implementation
- Intervention acceptability
  - Mean number of KIU! modules completed by participants
  - Cost of intervention delivery per participant
  - Cost of intervention delivery per infection averted

#### Adoption & Maintenance
- Not comparable between arms

#### Effectiveness
- Change in unprotected sex
- 12-mo rectal STI incidence
- 12-mo PrEP initiation
- 1+ HIV test(s) over 12 mos
**Northwestern**

**Utilize financial strategies**
- Provide free at-home HIV/STI tests
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**Develop stakeholder interrelationships**
- Engage local CBOs, HDs, advocacy groups, researchers for referrals and recruitment strategies
- Links to resources

**Train and educate stakeholders**
- Training RAs and coordinators

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**Engage consumers**
- Streamlined recruitment and enrollment with minimal staff interaction
- Advertise via social media, dating apps
- Routine contacts with, monitoring by NU
- Intervene to enhance uptake, adherence

**Select Implementation Strategies**

**CBO**
- Paying CBOs offsets cost of implementing KIU (e.g., covers effort) and meets expectations.

**DTC**
- Providing incentives increases YMSM attitudes toward participation.

**CBO/DTC**
- Providing at-home testing makes it easier for YMSM to get tested.

**Select Outcomes**

**Mechanisms**

**Reach**
- Proportion of YMSM in county screened for KIU!
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**Keep it up!**

**Agency** – Adapt and tailor to context

**Utilize financial strategies**
- Incentive structures

**Develop stakeholder interrelationships**
- Links to resources

**Train and educate stakeholders**
- Training new staff, ongoing training

**Support clinicians**
- Reminders/reports to staff

**Engage consumers**
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**KIU! Platform**

**Engage consumers**
- Participant orientation
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Select Implementation Strategies

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- Adapt and tailor to context
  - Tailoring intervention to CBOs
- Utilize financial strategies
  - Monetary support to CBOs
- Develop stakeholder interrelationships
  - Identify and prepare champions
- Train and educate stakeholders
  - Develop educational materials
  - Training providers on KIU & recruitment
  - Ongoing capacity building assistance
- Change infrastructure/support clinicians
  - Links to resources

**DTC**
- Engage local groups to refer and improve recruitment strategies for YMSM
- Intervene to enhance uptake, adherence

**CBO**
- Identifying and assisting implementation champions at CBOs increases ownership, local control, accountability, and prioritization.

**DTC**
- Engaging local groups to refer and improve recruitment strategies for YMSM increases local YMSM awareness of KIU.

Mechanisms

**CBO**
- Reach
  - Proportion of YMSM in county screened for KIU!
  - Proportion of invited YMSM who begin KIU!
  - Proportion of KIU! participants that are Black or Latino
- Implementation
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| Identifying and preparing champions | 
| Train and educate stakeholders | Training RAs and coordinators 
| Developing educational materials | 
| Engaging providers with KIU! and recruitment | 
| Ongoing capacity building assistance | 

| **Change infrastructure/support clinicians** | **Train and educate stakeholders** |
| Hosts and maintains technology | Training new staff, ongoing training |

| **Agency – Adapt and tailor to context** | 
| Utilizing financial strategies | Incentive structures 
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| **Support clinicians** | Reminders/reports to staff |
| **Engage consumers** | Outreach to YMSM 
| | Intervene to enhance uptake, adherence |

### Mechanisms

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### Select Outcomes

| CBO/DTC: Training staff on how to “sell” and use KIU and how to reach YMSM will increase their skill in engaging and enrolling YMSM. |

| **CBO:** Capacity building assistance will help CBOs integrate KIU into their regular workflows. |

| Reach | 
| Proportion of YMSM in county screened for KIU! |
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| Proportion of KIU! participants that are Black or Latino |

| Implementation | 
| Intervention acceptability | Mean number of KIU! modules completed by participants |
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**DTC**
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**Mechanisms**

**KIU! Platform**
- Engage consumers
  - Participant orientation
  - Automated reminders sent from system
- Change infrastructure/support clinicians
  - Custom-built patient tracking system

**CBO: Hosting and maintaining technology at Northwestern**
- Participant tracking platform built into KIU! platform makes it easier and more efficient for staff to track participant progress.

**CBO/DTC (KIU!):**
- Additional in-house tracking and messaging systems allow KIU! staff to efficiently engage and remind participants.

**Select Outcomes**

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**Engage consumers**
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- Intervene to enhance uptake, adherence

**CBO/DTC (KIU!): Various forms of dissemination and participant-engagement activities and reminders increase initial awareness of KIU! among YMSM and appeal of the intervention. Once enrolled, strategies will remind them to complete all intervention content.**

**Mechanisms**

**KIU! Platform**
- **Engage consumers**
  - Participant orientation
  - Automated reminders sent from system
- **Change infrastructure/support clinicians**
  - Custom-built patient tracking system

**Select Outcomes**

**Reach**
- Proportion of YMSM in county screened for KIU!
- Proportion of invited YMSM who begin KIU!
- Proportion of KIU! participants that are Black or Latino

**Implementation**
- Intervention acceptability
- Mean number of KIU! modules completed by participants
- Cost of intervention delivery per participant
- Cost of intervention delivery per infection averted

**Adoption & Maintenance** not comparable between arms

**Effectiveness**
- Change in unprotected sex
- 12-mo rectal STI incidence
- 12-mo PrEP initiation
- 1+ HIV test(s) over 12 mos

have fun. stay safe.
keep it up!
Implications

- Understanding how best to scale up eHealth interventions is important in helping to end the HIV epidemic.
- Implementation research in this area must be pragmatic and scientifically rigorous.
- Given substantial evidence of efficacy without evidence of “voltage drop” during implementation, KIU! is an ideal program study scale-up.
- Given its two macro-strategies, it is also a good example of how the IR logic model, strategies, and strategy specification are used in a later-stage IR project.
- Lessons learned from KIU! 3.0 will pave the way for implementing the many HIV eHealth programs currently undergoing efficacy testing.
Thank you KIU! funders, collaborators, and staff

R01MH118213